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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

061018-0008-US

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Application Number

09/643,554

Filed

August 22, 2000

First Named Inventor

Fiedotin et al.

Art Unit

3626

Examiner

Christoper L.Gilligan

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)☒ attorney or agent of record.
Registration number 45,645☐ attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 _____

Signature

Dion M. Bregman

Typed or printed name

650/843-4000

Telephone number

September 7, 2006

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.



*Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Express Mail No.: EV 533 737 429 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Fiedotin *et al.*

Serial No. 09/643,554

Filed: August 22, 2000

For: *Method for Renewing Medical
Prescriptions*

Confirmation No.: 9688

Group Art Unit: 3626

Examiner: Gilligan, Christopher L.

Attorney Docket No.: 061018-0008-US

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450

Sir:

Pursuant to the July 12, 2005 Official Gazette (OG) Notice, Applicants file this Pre-Appeal Brief Request for Review of the Examiner's final rejections contained in the June 14, 2006 Final Office Action.

In the June 14, 2006 Office Action, the Examiner finally rejected claims 1, 3-7, 11, 15, 16, 18, 20, 21, and 26-35 under 35 U.S.C. 102(b) as anticipated by Halvorson ("*Halvorson*", U.S. Pat. No. 4,847,764). The Examiner also finally rejected the remaining claims under 35 U.S.C. 103(a) as unpatentable over *Halvorson* and different references for each set of rejected claims. As will be shown below, the anticipation rejections are improper because (i) for independent claims 1 and 31 the prior art references do not teach or suggest (a) generating a prescription renewal request, (b) transmitting said prescription renewal request to a prescriber, (c) receiving a renewal prescription, or (d) notifying a dispenser to fill said renewal prescription.

A. Halvorson does not disclose, teach, or suggest renewal prescriptions

The present inventions alleviate the inefficiencies that doctors face daily with having to renew prescriptions. For example, doctors waste an inordinate amount of time each day attending to calls from pharmacies requesting authorization to renew existing prescriptions. *See* specification at pg. 3, line 30 – pg. 4, line 21 and pg. 5, ll. 13-20. The present inventions, as claimed, address these problems by simplifying the renewal prescription process. Renewal prescriptions are a term of art that are defined on page 3 of the present application as "a new prescription based at least in part upon the original prescription, *i.e.* for a pharmaceutical drug in the same therapeutic category (often the identical pharmaceutical drug), requiring a new authorization from the physician."

Unrelated to the present invention, *Halvorson* addresses the problems of untimely and error-prone dispensing of medications within health care institutions. *See Halvorson* Background Section.

To address these problems, *Halvorson* teaches an electro-mechanical dispensing cabinet which dispenses “orders” for medications, which are inserted by pharmacists, to authorized health care institution personnel on demand. *See Halvorson* col. 2, ll. 41-45, col. 3, ll. 28-31, and col. 4, ll. 28-31.

A “renewal prescription” of the present invention cannot be interpreted to include an “order” inserted by pharmacists into the electro-mechanical dispensing cabinet of *Halvorson*. First, *Halvorson* only mentions prescriptions in the claims and cursorily in the background of the application. Indeed, *Halvorson* discloses orders that are inserted and dispensed from a health care institution’s electro-mechanical dispensing cabinet, and not the prescriptions that may have led to these dispensing orders in the first place.

Second, *Halvorson* distinguishes orders from prescriptions. For example, claim 22 of *Halvorson* states that the dispensing system holds “medication order data specifying medication orders for patients in said institution in accordance with medication prescriptions for said patients . . .” In other words, while the order is based on a prescription, it is not the prescription itself.¹

Third, a prescription is different from an order because a prescription can be used to purchase a drug from any of:

a retail-store pharmacy, a mail-order pharmacy, an on-line pharmacy, a PBM acting as a pharmacy, a PBM acting in conjunction with any of the former, or an entity or person authorized to dispense prescription pharmaceuticals.

See Present Application at page 7, lines 18-20 (emphasis added). The orders disclosed in *Halvorson*, however, can only result in a drug being delivered to a patient while that patient is within the health care institution, because *Halvorson* only teaches an automated drug dispensing machine used within a health care institution.

Halvorson also fails to disclose, teach, or suggest renewal prescriptions. The only mention of the terms “renew” or “renewal” in *Halvorson* relates to orders and not prescriptions. As shown below, authorization of an order before it is renewed in the dispensing system of *Halvorson* cannot be likened to electronically obtaining a renewal prescription from a prescriber, as required by the present claims.

B. Halvorson does not disclose, teach, or suggest generating a prescription renewal request

On page 2 of the Final Office Action the Examiner alleges that *Halvorson* discloses:

generating a prescription renewal request for the renewal of said prescription . . . (see column 5, lines 29-32 the Examiner considers informing each physician of orders that require renewal to be generation of a prescription renewal request).

(Emphasis added). The cited portion of *Halvorson* discloses a report produced at a dispensing

¹ The dispensing process typically occurs well after the dispenser is notified to fill a prescription, *i.e.*, after the final step in claims 1 and 31 of the present invention.

location, *i.e.* a station located in the ward of a health care institution,² of all orders that will be discontinued within 24 hours, “if the orders are not renewed.” *See Halvorson*, col. 5, lines 29-32 (emphasis added). A report listing those medications that will soon run out in an electro-mechanical dispensing cabinet is not a generation of a prescription renewal request.

Furthermore, the report disclosed in *Halvorson* is nothing more than a summary of information listing drugs soon to be discontinued, and does not request the prescriber to do anything with the information. Thus, the report cannot be said to be a prescription renewal request in which the prescriber is requested to renew a prescription. What, if anything, is done with the information presented in the report is at best unclear from the teaching of *Halvorson*. For this reason alone, *Halvorson* does not disclose, teach, or suggest the limitation of generating a prescription renewal request.

C. Halvorson does not disclose, teach, or suggest transmitting said prescription renewal request to a prescriber

The preamble of independent claims 1 and 31 requires that the method is performed via an electronic network. The Examiner states that “the steps recited in the body of the claims make no reference to the electronic network recited in the preamble.” *See* pg. 11 of the 6/14/06 Final Office Action. Applicants respectfully disagree that the claim as a whole does not include the electronic network. “Where a patentee uses the claim preamble to recite structural limitations of his claimed invention, the PTO and courts give effect to that usage.” *See Applied Materials, Inc. v. Advanced Semiconductor Materials America, Inc.*, 98 F.3d 1563 (Fed. Cir. 1996). Moreover, “[i]f the claim preamble, when read in the context of the entire claim, recites limitations of the claim, . . . , then the claim preamble should be construed as if in the balance of the claim.” *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298 (Fed. Cir. 1999). As both independent claims require steps of “transmitting,” “receiving,” and “notifying,” the claim preamble, when read in the context of the entire claim, requires the structural limitation of an electronic network, and in particular, communicating over an electronic network. As such, the “electronic network” of the preamble is indeed a limitation of all of the present claims.

The Examiner alleges, in rejecting claims 1 and 31, that *Halvorson* discloses “transmitting said prescription renewal request to a prescriber (see column 5, lines 29-32).” Applicants respectfully disagree for the simple reason that the report in *Halvorson* (col. 5, lines 29-32) is not transmitted to a prescriber, and instead is printed at a “dispensing location.” The present specification defines a prescriber (emphasis added) as:

² Dispensing station and dispensing location are terms left undefined in *Halvorson*, however claim 1 in *Halvorson* claims “one or more dispensing stations located in the wards of said health care institution.” *See Halvorson*, col. 24, lines 22-23. The specification in *Halvorson* uses the terms dispensing location and dispensing station interchangeably, as the following passage demonstrates. “The dispensing system can also support dispensing locations that do not have

a person having the authority to authorize a dispenser to dispense a pharmaceutical. Depending on the laws of any particular jurisdiction, such a person includes, without limitation, **physicians, physician assistants, registered nurses, or persons acting under the direction of these individuals.**

See Present Application at page 7, lines 20-24. Independent claims 1 and 31, therefore require transmitting the prescription renewal request to a physician, physician assistant, or a registered nurse over the electronic network. In contrast, *Halvorson* only discloses printing the report containing a list of medication that is soon to run out in automated dispensing machine in a ward of a health care institution. As such, *Halvorson* does not disclose, teach, or suggest transmitting the renewal request to a prescriber over an electronic network, as recited in claims 1 and 31.

D. Halvorson does not disclose, teach, or suggest receiving a renewal prescription from a prescriber

As discussed above, *Halvorson* does not disclose generating a prescription renewal request, but rather discloses printing a daily report of medication that is soon to run out in an automated dispensing machine. Since *Halvorson* only discloses discontinued orders, and not prescriptions, *Halvorson* neither teaches nor suggests receiving a renewal prescription – much less a request for a renewal prescription.³

As support for this limitation, the Examiner quotes a passage from *Halvorson* that states that “[n]o medications are dispensed without first being authorized by a physician.” This means what it says, namely that no medications can be dispensed without having been first authorized by a physician. This does not mean (i) that a prescription is received from a physician, (ii) that the prescription is a renewal prescription, (iii) that the prescription is received over an electronic network, and (iv) that the renewal prescription is received in response to the prescription renewal request. First, *Halvorson* does not disclose how the authorization is given, and certainly does not disclose that the authorization is given in the form of a prescription. For example, the authorization may be a verbal authorization or a check-mark on a patient’s chart, *i.e.*, not a prescription at all. Second, *Halvorson* does not disclose that the authorization take the form of a renewal prescription, which is a well known term of art that is different from a regular prescription. Third, *Halvorson* does not disclose that an order is received over an electronic network, let alone that a renewal prescription is received over an electronic network. Finally, *Halvorson* only teaches that prior authorization is required before dispensing a medication, but not that a renewal prescription is received in response to the prescription renewal request. For example, authorization may be given by a doctor that refers a patient to a hospital, or by the initial examining doctor, as long as it is before medication is dispensed. Therefore, while authorization is required prior to dispensing medication, such authorization only needs to occur

mechanical dispensers, as shown in FIG. 1, but the stations must have, at least, a video display unit 30 with a keyboard and preferably a printer 21.” See *Halvorson*, col. 5, lines 36-40 (emphasis added).

³ The renewal prescription is the prescription itself and is different to the prescription renewal request.

once and is certainly not given in response to a prescription renewal request, as required by the present claims.

E. Halvorson does not disclose, teach, or suggest notifying a dispenser to fill said renewal prescription

As noted above, *Halvorson*'s orders can only be filled at the health care institution's automated dispenser and not at any pharmacy like a prescription. By contrast, as explained above, the dispenser claimed in claims 1 and 31 includes "a retail-store pharmacy, a mail-order pharmacy, an on-line pharmacy, . . . or an entity or person authorized to dispense prescription pharmaceuticals." See Present Application at page 7, lines 18-20

The Examiner cites to col. 4, lines 28-32 of *Halvorson*, which states that "[t]he preferred dispensing station will have a dispenser 32 which contains a plurality of medications that may be automatically dispensed to authorized personnel on demand." As *Halvorson* only teaches an electromechanical device that dispenses a particular medication at a dispensing station in a ward of a health care institution, *Halvorson* cannot teach or suggest the claimed "dispenser," which is defined in the specification to be an entity or a person. Therefore, *Halvorson* does not disclose, teach, or suggest the claimed step of "notifying a dispenser to fill said renewal prescription."

Moreover, the notifying is performed over the electronic network. *Halvorson* does not disclose, teach, or suggest notifying a dispenser to fill a renewal prescription, let alone notifying the dispenser over an electronic network.

F. Conclusion

In light of the above, it is respectfully submitted that the Examiner has failed to establish a *prima facie* case of obviousness of the independent claims. Accordingly, the Examiner is respectfully requested to withdraw these rejections and allow this application which has been pending for over six years.

If there are any fees or credits due in connection with the filing of this Amendment, including any fees required for an Extension of Time under 37 C.F.R. Section 1.136, authorization is given to charge any necessary fees to our Deposit Account No. 50-0310 (order No. 061018-0008-US). A copy of this sheet is enclosed for such purpose.

Date: September 7, 2006

Respectfully submitted,



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